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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,567	03/07/2002	Jonathan P. Wong	NEL-006	7851

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EXAMINER	
HILL, MYRON G	
ART UNIT	**PAPER NUMBER**
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/091,567	WONG ET AL.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/22/06 has been entered.

Claims 20-32 are under consideration.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 28 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has amended the claim and the rejection is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20-27 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wheeler *et al.* and Webb *et al.* in view of Sha *et al.* and Promega Catalog (the last two references previously cited).

The rejection is withdrawn in favor of the new rejection below (new reference).

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention is drawn to methods of treating or preventing or inducing long lasting immunity.

Applicant argues that the Office is being to limiting and narrow in the application of what is required by the Office in terms of patentability and that the specification shows that the liposomes are effective.

Applicant's arguments have been fully considered and not found persuasive.

The claims are not limited to the liposomal formulation taught and used in the specification or a formulation made in a similar manner. Applicant has not shown the protection of mice as disclosed correlated to the features as recited in claim 20 that the claimed methods (preventing and treating, and eliciting long lasting protection). It was previously noted that Sha *et al.* teach vaccine failure of some plasmid liposome formulations and the claims do not exclude those embodiements.

Thus, the rejection is maintained.

Rejections New or Modified

Claim Rejections - 35 USC § 103

Claims 20-27 and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis *et al.* in view of Sha *et al.* and Promega Catalog.

The invention is drawn to a liposomal plasmid influenza vaccine.

Davis *et al.* teach a liposomal vaccine composition comprising a plasmid expressing antigen that is encapsidated in a lipid that is delivered intranasally (column 26 middle). Davis *et al.* also teach that the antigen can be influenza (column 18, lines 8-9).

Davis *et al.* do not teach influenza HA or plasmid pCI.

Sha *et al.* (previously cited) is used to teach that Influenza HA is well known in the art as an antigen that can produce a protective immune response.

Promega Catalog (previously cited) teaches pCI plasmid with a CMV promoter and enhancer, that it shows strong constitutive expression in many cell types and has a T7 promoter for *in vitro* translation. The plasmid is known and has been used in prior art publications.

One of ordinary skill in the art would know to use expression vectors such as the Promega pCI because it is optimized for expression and Davis *et al.* teach that one of skill in the art can select plasmids for use as well as clone into it for use as a vaccine an HA of influenza because it is known to be antigenic and a protective.

Thus, it would be *prima facie* obvious to make and use a liposomal influenza plasmid vaccine of Davis *et al.* with art known components HA and pCI plasmid with the expectation of success.

Claims 20 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wheeler *et al.*, Webb *et al.*, Yau-Young, and Davis *et al.* in view of Sha *et al.*

The invention is drawn to a formulation of liposome for making plasmid influenza vaccine and a method of making the liposomes.

Wheeler *et al.* teach a liposome formulation. They teach a lipid to DNA ratio of 25 to 1 and method of making liposomes (page 279, column 2, lower half).

Wheeler et al. define the critical parameter as the DODAC concentration (Figure 1 b) and the best result is with DOPE and the highest encapsidation is between 6-8% DODAC. Wheeler et al. used 6% but it is clear that 7% falls at the middle of the peak. Wheeler et al also states that the maximum encapsidation is varies from batch to batch by about 1% (273, column 1, top). None of the other parameters are taught as critical.

Wheeler et al. do not teach rotaevaporation, C8 cermide or influenza plasmids.

Yau-Young teach that rotaevaporation is an art known method for the formulation of lipids and produces high encasidation efficiencies (column13, first paragraph).

Webb *et al.* teach C8 cermide.

Sha *et al.* (previously cited) is used to teach that Influenza HA is well known in the art as an antigen that can produce a protective immune response.

One of ordinary skill in the art at the time of invention would have been motivated to modify the cermide of Wheeler et al. with the C8 of Webb et al because Wheeler et al. show that the between two lengths tested (C14 and C20), the shorter worked better (Figure 7). The next lower size is C8 as shown by Webb et al.

One of ordinary skill in the art would know as taught by Yau-Young that there are many methods of making liposomes (column 9, last paragraph) and woud be motivated to use a procedure that is efficient.

Thus, it would be *prima facie* obvious to modify the liposomes of Wheeler *et al.* to use the C8 of Webb *et al.* and the efficient rotaevoration method of Yau-Young to make a liposomal influenza plasmid with expectation of success of making a liposomal vaccine with an encapsidated plasmid that encodes influenza hemagglutinin.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Myron G. Hill
Patent Examiner
15 FEB 2007

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